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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,291	03/12/2004	Zoltan G. Toth	2664/63005	8286
26646	7590	08/21/2006	EXAMINER	
KENYON & KENYON LLP ONE BROADWAY NEW YORK, NY 10004			STITZEL, DAVID PAUL	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 08/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/800,291

Applicant(s)

TOTH ET AL.

Examiner

David P. Stitzel, Esq.

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 14,27 and 60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15-26 and 28-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9/20/06; 11/8/04.
- 4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. 8/8/06.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

**OFFICIAL ACTION**

***Restriction/Election***

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 1-13, 15-26 and 28-59 are drawn to a stable mixture of crystalline polymorph Form I and Form II of desloratadine and a pharmaceutical formulation comprising said stable mixture, as classified in class 514, subclass 290.
- II. Claims 14, 27 and 60 are drawn to a method of treating allergenic reactions in a mammal comprising administering said pharmaceutical formulation comprising said stable mixture to said mammal, as classified in class 424, subclass 810.

Inventions I and II are related as a product and a method of using said product, respectively. The inventions can be shown to be distinct if either or both of the following can be shown that: (1) the method of using the product as claimed can be practiced with another materially different product; or (2) the product as claimed can be used by another method that is materially different from the instantly claimed method of using said product. See MPEP § 806.05(h). In the instant case, a stable mixture of crystalline polymorph Form I and Form II of desloratadine and a pharmaceutical formulation comprising said stable mixture as claimed in Invention I can be used by another method that is materially different from the method claimed in Invention II. For example, as opposed to a method of treating allergenic reactions in a mammal comprising administering said pharmaceutical formulation to said mammal as claimed in Invention II, the pharmaceutical formulation claimed in Invention I may alternatively be used to treat nasal congestion and sleeping disorders.

Because these inventions are independent and distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, the prior art search required for each respective invention would be divergent, thereby causing an undue search burden.

As a result, restriction for examination purposes as indicated is proper. Applicants are therefore required under 35 U.S.C. § 121 to elect a single invention for prosecution on the merits.

***Conclusion to Restriction Requirement***

The Examiner has required restriction between product, methods of making, and methods of using claims. Where Applicants elect claims directed to a product, and the product claim is subsequently found allowable, withdrawn methods of making and methods of using claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Methods of making and methods of using claims that depend from or otherwise include all the limitations of the patentable product claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined methods of making and methods of using claims will be withdrawn, and the rejoined methods of making and methods of using claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §§ 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and methods of making and methods of using claims may be maintained. Withdrawn methods of making and methods of using claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicants are advised that the methods of making and methods of using claims should be amended during prosecution either to maintain dependency on the

product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named Inventors is no longer an actual Inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

#### ***Election & Telephone Interview Summary***

Pursuant to a telephone interview held with the attorney of record, namely Mr. Payam Moradian, Esq., on Tuesday, August 8, 2006, at approximately 1:30 PM EST, an election was made *with traverse* to prosecute the invention of Group I encompassing claims 1-13, 15-26 and 28-59. As a result and pursuant to 37 CFR § 1.142(b), claims 14, 27 and 60 are withdrawn from further consideration as being directed to a non-elected invention.

#### ***Status of Claims***

Claims 14, 27 and 60 are withdrawn from further consideration as being directed to a non-elected invention. As a result, claims 1-13, 15-26 and 28-59 are therefore examined herein on the merits for patentability.

#### ***Nonstatutory Double Patenting***

A nonstatutory double patenting rejection of the “obviousness-type” is based on a judicially created doctrine grounded in public policy so as to prevent not only the unjustified or improper timewise extension of the “right to exclude” granted by a patent, but also possible harassment by

multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re White*, 405 F.2d 904, 160 USPQ 417 (CCPA 1969); *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968); and *In re Sarett*, 327 F.2d 1005, 140 USPQ 474 (CCPA 1964).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned or assigned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. See MPEP § 804. However, this does not mean that one is absolutely precluded from all use of the patent disclosure. See MPEP § 804. For example, the specification can always be used as a dictionary to learn the meaning of a term in the patent claim. *In re Boylan*, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Furthermore, *those portions of the specification which provide support for the patent claims may also be examined and considered* when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. *In re Vogel*, 422 F.2d 438, 441-442, 164 USPQ 619, 622 (CCPA 1970). The court in *Vogel* stated that one must first “determine how much of the patent disclosure pertains to the invention claimed in the patent” because only “[t]his portion of the specification supports the patent claims and may be considered.” The court

in *Vogel* also pointed out that “this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. § 103, since only the disclosure of the invention claimed in the patent may be examined.”

1. Claims 1-13, 15-26 and 28-59 of the instant application are provisionally rejected under the judicially created doctrine of non-statutory obviousness-type double patenting as being unpatentable over conflicting claims 21-24 of copending U.S. Patent Application, Serial Number 11/283,276 (hereinafter the conflicting Toth ‘276 application).

More specifically, claims 1-13, 15-26 and 28-59 of the instant application are directed to a stable mixture of crystalline polymorph Form I and Form II of desloratadine and a pharmaceutical formulation comprising said stable mixture and a pharmaceutically acceptable excipient, wherein said stable mixture comprises: from about 20 wt. % to about 80 wt. % desloratadine Form I; from about 80 wt. % to about 20 wt. % desloratadine Form II; and said stable mixture is made by a process involving one or more organic solvents selected from the group consisting of: n-heptane; toluene; isopropanol; and mixtures thereof. Claims 14, 27 and 60 of the instant application are directed to a method of treating allergenic reactions in a mammal comprising administering said pharmaceutical formulation to said mammal.

Claims 21-24 of the conflicting Toth ‘276 application are directed to a mixture of crystalline polymorph Form I and Form II of desloratadine and a pharmaceutical formulation comprising said mixture, wherein said mixture comprises: from about 35 wt. % to about 82 wt. % desloratadine Form I; from about 65 wt. % to about 18 wt. % desloratadine Form II; and from about 50 ppm to about 4000 ppm of one or more organic solvents selected from the group consisting of: n-hexane; n-heptane; toluene; ethyl acetate; isobutyl acetate; butanol; isobutanol; chloroform; and mixtures thereof. Claim

25 of the conflicting Toth '276 application is directed to a method of treating allergenic reactions in a mammal comprising administering said pharmaceutical formulation to said mammal.

However, while the conflicting Toth '276 application does not claim the physicochemical properties (i.e., melting temperature, stability, flowability, solubility, dissolution rate, and bioavailability) of said stable mixture, as claimed in claims 4-13, 17-26 and 31-36 of the instant application, it is well within the purview of the skilled artisan to measure the physicochemical properties of said stable mixture by measuring, for example, the melting temperature and resistance to polymorphic transformation, chemical degradation and decomposition that said stable mixture possesses. One of ordinary skill in the art at the time the instant application was filed would have been motivated to conduct routine experimentation in order to determine whether the physicochemical properties (i.e., melting temperature, stability, flowability, solubility, dissolution rate, and bioavailability) of said stable mixture, to be incorporated into a pharmaceutical formulation, are constant and thus exhibit batch-to-batch consistency and uniformity from a drug manufacturing and quality assurance perspective.

As a result, although claims 1-13, 15-26 and 28-59 of the instant application are not identical to claims 21-24 of the conflicting Toth '276 application, the aforementioned claims are not patentably distinct each from the other because said claims are substantially overlapping in scope, with respect to said organic solvents and said weight percent ranges and ratios of crystalline polymorph Form I and Form II of desloratadine, as discussed hereinabove, as discussed hereinabove. This is a provisional non-statutory double patenting rejection since the conflicting claims have not yet been patented.

It should be mentioned however that while claims 14, 27 and 60 of the instant application are currently withdrawn from further consideration as being directed to a non-elected invention, in the event that the elected product claims are found allowable, the requirement for restriction between the



elected product claims and the non-elected method of using claims will be withdrawn, and the rejoined method of using claims will be fully examined for patentability in accordance with 37 CFR 1.104 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995). In the event of rejoinder, Applicants are advised that claims 14, 27 and 60 of the instant application would be provisionally rejected under the judicially created doctrine of non-statutory obviousness-type double patenting as being unpatentable over conflicting claim 25 of the conflicting Toth '276 application. This would be a provisional non-statutory double patenting rejection since conflicting claim 25 of the conflicting Toth '276 application have not yet in fact been patented and are substantially overlapping in scope (i.e., drawn to a method of treating allergenic reactions in a mammal comprising administering said pharmaceutical formulation to said mammal) to claims 14, 27 and 60 of the instant application.

***Claim Rejections - 35 U.S.C. § 103***

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 103, which forms the basis of the obviousness rejections as set forth under this particular section of the Official Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-13, 15-26 and 28-59 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 6,506,767 (hereinafter the Schumacher '767 patent).

Claims 1-13, 15-26 and 28-59 of the instant application are directed to a stable mixture of crystalline polymorph Form I and Form II of desloratadine and a pharmaceutical formulation comprising said stable mixture and a pharmaceutically acceptable excipient, wherein said stable mixture comprises: from about 20 wt. % to about 80 wt. % desloratadine Form I; from about 80 wt. % to about 20 wt. % desloratadine Form II; and said stable mixture is made by a process involving one or more organic solvents selected from the group consisting of: n-heptane; toluene; isopropanol; and mixtures thereof. The pharmaceutical formulation of the instant application is useful for treating allergic reactions in a mammal.

With respect to claims 1-3, 15, 16, 28-30, 37 and 49 of the instant application, the Schumacher '767 patent teaches a stable mixture of crystalline polymorph Form I and Form II of desloratadine and a pharmaceutical formulation comprising said stable mixture and a pharmaceutically acceptable excipient; wherein said stable mixture comprises from about 1 wt. % to about 15 wt. % polymorph Form I of desloratadine and from about 99 wt. % to about 85 wt. % polymorph Form II of desloratadine; and wherein said stable mixture is made by a process involving one or more organic solvents selected from the group consisting of: n-hexane; ethyl acetate; and mixtures thereof (abstract; column 1, lines 9-50 and 64-66; column 2, lines 50-52 and 65-67; column 3, lines 53-67; column 4, lines 1-41; column 8, lines 51-67; column 9; column 10; column 11; column 12, lines 1-8; claims 1, 2, 7, 8, 9 and 14-16).

With respect to claims 1-13, 15-26 and 28-59 of the instant application, although the Schumacher '767 patent teaches a stable mixture comprising from about 1 wt. % to about 15 wt. % polymorph Form I of desloratadine and from about 99 wt. % to about 85 wt. % polymorph Form II of

desloratadine (column 3, lines 60-65; claims 8, 9, 14 and 15), the Schumacher '767 patent does not explicitly teach the instantly claimed stable mixture comprising from about 35 wt. % to about 82 wt. % polymorph Form I of desloratadine and from about 65 wt. % to about 18 wt. % polymorph Form II of desloratadine, wherein said stable mixture exhibits the instantly claimed melting temperature and stability (i.e., resistance to polymorphic transformation, chemical degradation and decomposition).

However, while the Schumacher '767 patent does not explicitly teach the instantly claimed weight percent ranges and ratios of polymorph Form I to Form II of desloratadine present within said stable mixture, the Schumacher '767 patent teaches that various solvent systems comprising a plurality of different organic solvents, which are routinely utilized by those of ordinary skill in the chemical, medicinal and pharmaceutical arts for synthesis and purification (i.e., recrystallization) purposes, yielded various stable mixtures containing respective ratios of polymorph Form I to Form II of desloratadine (column 4, lines 12-41). In addition, while the Schumacher '767 patent does not explicitly teach the instantly claimed melting temperature and stability of said stable mixture, the Schumacher '767 patent teaches that said stable mixtures are suitable for incorporation into pharmaceutical formulations that meet the Good Manufacturing Practice (GMP) requirements of the Food and Drug Administration (FDA), thereby directly indicating that said stable mixtures and pharmaceutical formulations comprising said stable mixtures possess constant physicochemical properties, such as melting temperature and resistance to polymorphic transformation, chemical degradation and decomposition (column 1, lines 34-41; column 3, lines 60-65; column 4, lines 12-41; claims 8, 9, 14 and 15).

It is well within the purview of the skilled artisan to determine the optimal solvent system comprising a single specific organic solvent or a particular organic solvent/anti-solvent stable mixture for utilization in synthesizing and/or recrystallizing a stable mixture having a desired weight percent

range and ratio of polymorph Form I to Form II of desloratadine. It is also well within the purview of the skilled artisan to measure the physicochemical properties of said stable mixture by measuring, for example, the melting temperature and resistance to polymorphic transformation, chemical degradation and decomposition that said stable mixture possesses. One of ordinary skill in the art at the time the instant application was filed would have been motivated to conduct routine experimentation in order to determine an optimal solvent system that is particularly useful for obtaining, on a routine and reproducible basis, a stable mixture having a consistent desired weight percent range and ratio of polymorph Form I to Form II of desloratadine, so that the physicochemical properties (i.e., melting temperature, stability, flowability, solubility, dissolution rate, and bioavailability) of said stable mixture, to be incorporated into a pharmaceutical formulation, are constant and thus exhibit batch-to-batch consistency and uniformity from a drug manufacturing and quality assurance perspective. The Schumacher '767 patent further teaches that not only are each of polymorphs Form I and Form II of desloratadine independently useful for treating allergic reactions in mammals upon individual incorporation into a pharmaceutical formulation, but also stable mixtures containing respective weight percent ranges and ratios of polymorph Form I to Form II of desloratadine upon combined incorporation into a pharmaceutical formulation are also useful for treating allergic reactions in mammals, as instantly claimed (abstract; column 3, lines 60-65; claims 8, 9, 14 and 15).

Merely changing the form, purity, or another characteristic of an old product, the utility remaining the same as that of the old product, does not render the claimed product patentable. *Ex parte Hartop*, 139 USPQ 525 (Bd. App. 1962). However, the principle of law enunciated in *Ex parte Hartop* has been substantially discredited in *In re Cofer*, 354 F.2d 664, 667-668, 148 USPQ 268, 270-271 (CCPA 1966). Factors to be considered in determining whether a purified form of an old product is obvious over the prior art include: whether the instantly claimed chemical compound or composition

has the same utility as closely related chemical compounds or compositions in the prior art; and whether the prior art reasonably suggests either the particular form or structure of the instantly claimed chemical compound or composition, or suitable methods of obtaining that particular form or structure of the instantly claimed chemical compound or composition. See e.g., MPEP § 2144.04, and *In re Cofer*, 354 F.2d 664, 667-668, 148 USPQ 268, 270-271 (CCPA 1966) (Claims to the free-flowing crystalline form of a compound were held unobvious over references disclosing the viscous liquid form of the same compound because the prior art of record did not suggest the claimed compound in crystalline form or how to obtain such crystals.). “Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” See *In re Aller*, 105 USPQ 233, 235 (CCPA 1955). “The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.” See *Peterson*, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). “It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ... [T]he idea of combining them flows logically from their having been individually taught in the prior art.” See e.g., MPEP § 2144.06 and *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

### ***Conclusion***

Claims 1-13, 15-26 and 28-59 are rejected because the claimed invention would have been anticipated and/or prima facie obvious to one of ordinary skill in the art at the time the invention was made since each and every element of the claimed invention, as a whole, is disclosed in and/or would have been reasonably suggested by the teachings of the cited prior art references.

***Remarks***

The following is a list comprising: a Pre-Grant Patent Application Publication (which although does not qualify as prior art under 35 U.S.C. § 102, due to a filing date of April 16, 2003, as the instant application claims priority to a U.S. Provisional Patent Application filed on March 12, 2003, does in fact shed light on the state of the art at the time the instant application was filed); a prior art patent; and prior art scientific journal article publications made of record and considered pertinent to the Applicant's disclosure, but are not however currently relied upon in construing the claim rejections as set forth hereinabove:

- U.S. Pre-Grant Patent Application Publication 2006/0058334 ([0001]-[0003] and [0027], which are illustrative of the state of the art at the time the instant application was filed);
- U.S. Patent 4,659,716 (abstract; column 1, lines 1-68; column 2, lines 1 and 2; column 6, lines 62-68; column 7; column 8, lines 53-56; column 16, lines 4-25, Example III; column 17, lines 64-68, Example V; column 18, lines 1-50, Example VI; column 21, lines 33-44, Example VIII);
- Tiwary AK, Modification of Crystal Habit and Its Role in Dosage Form Performance, Drug Development and Industrial Pharmacy, Volume 27, Number 7, pp. 699-709 (2001);
- Gu CH, Young V, Grant DJW, Polymorph Screening: Influence of Solvents on the Rate of Solvent-Mediated Polymorphic Transformation, Journal of Pharmaceutical Sciences, Vol. 90, No. 11 (November 2001); and
- Kawashima Y, Aoki S, Takenaka H, Miyake Y, Preparation of Spherically Agglomerated Crystals, Journal of Pharmaceutical Sciences, Vol. 73, No. 10, pp. 1407-1410, 1408 (October 1984) (Table I illustrating a plurality of different organic solvents, which are routinely utilized in solvent systems by those of ordinary skill in the chemical, medicinal and pharmaceutical arts for synthesis and purification (i.e., crystallization/recrystallization) purposes).

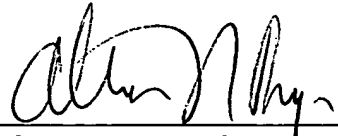
***Contact Information***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to David P. Stitzel, M.S., Esq., whose telephone number is 571-272-8508. The Examiner can normally be reached on Monday-Friday, from 7:30AM-6:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Johann Richter, Ph.D., Esq., can be reached at 571-272-0646. The central fax number for the USPTO is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published patent applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished patent applications is only available through Private PAIR. For more information about the PAIR system, please see <http://pair-direct.uspto.gov>. Should you have questions about acquiring access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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